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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901382 for a patent by ROBERT BAIRD WATSON as filed on 25 March 2003.

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Seventh day of April 2004

J. Billingsley

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TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: HYPODERMIC SYRINGE

Applicant: ROBERT BAIRD WATSON

The invention is described in the following statement:

HYPODERMIC SYRINGE

This invention relates to a non-reusable hypodermic syringe. The syringe is applicable for the administration of liquid medicines, pharmaceuticals, drugs and other solutions into human bodies, and it will be convenient to hereinafter disclose the invention in relation to that exemplary application. However, it is to be appreciated that the invention is not limited to that application. In that regard, the syringe may also be applicable to taking blood samples or other liquid from human bodies for analysis.

Australian patent application 2002953573 discloses a non-reusable hypodermic syringe, and the entire contents of the specification of that application is incorporated herein by reference.

The syringe of the above mentioned patent application is very effective in preventing multiple use and also enabling safe disposal. However, the complexity of the means for controlling the enabling and disabling of the syringe leads to manufacturing costs which are high relative to other syringes.

It is an object of the present invention to provide a syringe of simpler construction and lower manufacturing cost whilst retaining effectiveness against misuse and abuse.

In broad terms, the present invention provides a syringe including:

a syringe casing;

a syringe body within the casing and controllably movable relative thereto;

a hollow needle connected to the syringe body and extending from the casing for use of the syringe; and

a plunger reciprocally movable within the body for drawing and ejecting liquid through the needle.

The syringe also includes control means enabling the syringe to initially draw and subsequently eject a single charge of liquid through the needle, whereupon movement of the syringe body relative to the casing disables the syringe.

In at least one preferred form, the syringe casing is elongate with opposed forward and rear ends. In one form, the casing is tubular and, in one preferred form, the casing is cylindrical in cross sectional shape with inner and outer side surfaces.

In one preferred form, the syringe tubular casing is at least substantially closed at each end. In one form, the casing is sealed at each end except for access openings, the purposes of which will become more apparent hereinafter.

In at least one preferred form, the syringe body is elongate with opposed forward and rear ends. In this form, the body extends along within the casing for movement therealong. In one preferred form, the casing and body are orientated with their forward ends in the same one direction and the rear ends in the same opposite directions.

In one preferred form, the syringe body is controllably movable between positions in which the syringe is enabled and disabled. In the enabled position, the body is positioned toward the forward end of the casing, whilst in the disabled position the body is positioned further away from the forward end of the casing. In one preferred form, in the enabled position the body is positioned with its forward end adjacent the forward end of the casing. In this preferred form, in the disabled position the body is positioned with its forward end spaced from the forward end of the casing, and its rear end may be adjacent the rear end of the casing.

In one preferred form, in moving between the enabled and disabled position, the body moves through a disabling position. Thus, the body is movable from the enabled position to the disabling position and then to the disabled position. In the disabling position the body is positioned for disablement of the syringe.

In one preferred form, the body is tubular. That tubular body is axially slidable within the casing, in this form. In one form, the tubular body is also rotatably slidable about its longitudinal axis relative to the casing. In one form, the tubular body is cylindrical in cross sectional shape and is a neat sliding fit within the tubular casing.

In one preferred form, the body is rotatably slidable from the enabled position to the disabling position, and axially slidable from the disabling position to the disabled position.

In at least one preferred form, the hollow needle is connected to the forward end of the syringe body for movement therewith. The needle projects forwardly from the syringe body, and the forward end of the casing has an

access hole through which the needle passes in order to extend from the casing, in this form.

In one preferred form, the tubular body defines a chamber for holding a charge of liquid, and the needle is in communication with that chamber. In this way, the liquid charge can be drawn through the hollow needle into the chamber and subsequently ejected therefrom through the needle. Depending on the intended application of the syringe, the liquid might be, for example, an injectable solution drawn from a supply container and subsequently ejected/injected subcutaneously, or blood drawn subcutaneously from a body and subsequently ejected for analysis.

In one form, the tubular body is closed at the forward end, and the needle is fitted into that forward end so as to secure the needle to the body and place the needle in communication with the chamber. In this form, the needle is permanently fixed to the forward end of the tubular body.

In at least one preferred form, the plunger is reciprocally movable within the syringe body. In this form, the plunger includes a piston slidably movable within the body chamber, and an actuating stem extending from the piston and through the rear ends of the body and casing. The stem extends through an access hole in the otherwise closed rear end of the casing, in this form.

In one form, the stem is non-circular in transverse cross section, and the access hole in the rear end of the casing through which the stem extends is of the same cross sectional shape. In this way, the plunger can be reciprocated within the syringe body but is prevented from rotating relative thereto.

That stem is manually actuable in order to move the piston within the chamber so as to draw and eject liquid through the needle, in this form. To facilitate manual actuation of the stem, a thumb rest may be provided on an end of the stem, and one or more finger flanges may be provided on the syringe casing at or adjacent the rear end thereof, in a manner well understood by those skilled in the relevant art.

In one form, the piston has an outer surface that is in liquid sealing engagement with an inner surface of the tubular body defining the chamber. In this way, liquid can be drawn into and ejected from the chamber without leaking past the piston. Sealing engagement may be achieved by forming the piston, or at least the outer surface thereof, of sealing material, or by mounting one or

more sealing members such as sealing rings on the piston. The sealing material or member(s) may be composed of rubber.

In at least one preferred form, the control means includes at least one control member on the syringe casing, and at least one control member on the syringe body, the control members interengaging during syringe use to thereby effect the controlled movement of the body from the enabled position to the disabling position and then to the disabled position. In this form, the engagement between the control members also maintains the casing and body in relative longitudinal disposition while the syringe is enabled (i.e. while the body rotates from the enabled position to the disabling position), but is releasable under the controlled movement of the body for disabling the syringe. That release allows the body to move axially from the disabling to the disabled position and thereby retract the hollow needle into the casing so as to disable the syringe.

In one preferred form, the control members include at least one control cam and at least one cam follower, the cam and follower interengaging to effect the controlled movement.

In one preferred form, the or each cam is located on the body, and the or each cam follower is located on the casing, although it will be appreciated that these locations may be reversed.

In one preferred form, a single control cam follower is provided, that follower being located on an inner surface of the casing and extending generally inwardly therefrom. The cam follower is located adjacent the forward end of the casing, in this form.

In one preferred form, the cam follower includes a follower projection. That projection is fixed to the inner surface of the casing and projects inwardly therefrom, in this form. In one preferred form, the projection is a projecting pin.

In one preferred form, a single control cam is provided. That cam has at least one profiled camming surface for operative engagement by the single cam follower. The control cam is provided at an outer surface of the body, in facing relation to the cam follower during engagement therebetween. To that end, the control cam is located adjacent the forward end of the body, in this form.

In one preferred form, the control cam includes a camming groove or slot for receiving the cam follower pin therein. Thus, in one form the camming

groove or slot has an open top and opposed side faces. In this form, one or both of the side faces provides a camming surface. The control cam is set into the wall of the body, with the open top at the outer surface in one form. The camming groove has a closed bottom, whilst the camming slot has an open bottom, in this form. With this arrangement, during engagement, the follower pin extends through the open top into the camming groove or slot, and contacts a camming surface in order to apply a force to the body causing controlled movement of the body between the enabled and disabled positions.

In one form, the camming groove or slot is of a discrete length with opposite ends. At least one end is open, in this form, so as to allow the follower and cam to disengage for disablement of the syringe. Specifically, in one form, one end is open to allow the follower pin to exit from the camming groove or slot and so disengage from one another.

In one form, both ends of the camming groove or slot are open so that the pin can respectively enter and exit the groove or slot for the controlled movement of the syringe body. Thus, the pin enters the camming groove or slot at one end thereof and progressively travels therealong causing relative movement between the body and casing, in response to the camming surface profile, to move the body from the enabled position to the disabling position, before exiting from the other end of the camming groove or slot so as to disable the syringe.

In this form, the open end(s) of the groove or slot open through the forward end of the body.

In one preferred form, the cam has stages spaced therealong, each with a respective camming surface and with which the follower successively engages to control relative movement between the syringe body and casing. Those stages , in this form, include one in which the follower travels during initial drawing of a liquid charge into the body chamber (the charge control camming stage), and another in which the follower travels during ejection of the liquid charge from the chamber (the ejection control camming stage).

In one preferred form, the charge control camming stage prevents substantial longitudinal movement of the syringe body relative to the casing, but permits rotation of the body so that the follower travels relatively toward the ejection control camming stage. During that travel, the plunger is able to be

withdrawn relative to the body, so as to draw a charge of liquid into the chamber. That travel occurs and is completed during initial drawing movement of the plunger.

In order to achieve that relative movement of the body and casing, the camming surface in the charge control camming stage extends at an angle to the longitudinal axis of the syringe. In this way, engagement with the follower forces the body to rotate about the axis.

In order to limit relative travel of the cam and cam follower to that camming stage until the drawing movement of the plunger is completed, the control cam also includes a detent stage adjacent the end of the charge control camming stage. The detent stage temporarily prevents continued travel of the cam follower along the cam. In this form, the cam follower abuts the detent stage to prevent further movement.

In one form, the detent stage is provided by a reverse angling of the camming surface, relative to the camming surface in the charge control camming stage. The camming surface in the detent stage extends at least substantially parallel to the longitudinal axis of the syringe, in this form. In this way, the camming surfaces of the charge control camming stage and detent stage form an included angle into which the travelling cam follower is received and temporarily nested so as to impede continued relative travel between the control cam and cam follower.

In one preferred form, the ejection control camming stage prevents substantial longitudinal movement of the syringe body relative to the casing, but permits rotation of the body so that the cam follower continues to travel toward the exit end of the control cam. During this travel, the plunger is able to eject the charge of liquid from the chamber. That travel occurs, and is completed, during initial ejecting movement of the plunger, in this form. Completion of the travel positions the body in the disabling position, in this form.

In order to achieve that relative movement, the camming surface in the ejection control camming stage extends at an angle to the longitudinal axis of the syringe. In this way, engagement with the cam follower forces the body to rotate about the axis. The camming surface in this stage is on the opposite side face of the camming groove or slot to the side face providing the camming surface in the charge control camming stage, in this form.

In order to limit relative travel of the cam and cam follower, to that camming stage, until the charge ejection is completed, the control cam includes a further detent stage adjacent the end of the ejection control camming stage. The further detent stage temporarily prevents continued travel of the cam follower along the cam. In this form, the cam follower abuts the detent stage to prevent the further movement.

In one form, the further detent stage is provided by reverse angling of the camming surface. The camming surface in the further detent stage extends at least substantially parallel to the longitudinal axis of the syringe, in this form. In this way, the camming surfaces of the ejection control camming stage and further detent stage form an included angle into which the travelling cam follower is received and temporarily nested to inhibit continued relative travel between the cam and cam follower.

In one preferred form, the charge control camming stage and ejection control camming stage are arranged adjacent one another, interposed by the detent stage. In this arrangement, successive movements of the plunger draws a charge of liquid into the body chamber and then ejects that charge through the needle.

In an alternative form, however, the control means can permit one or more auxiliary movements of the plunger between charge drawing and ejection. By way of example, those movements may be to eject air from the needle following charge drawing, and to draw blood from a vein into the needle prior to charge ejection into that vein. In one preferred form, both movements can be provided by the control means.

To that end, in this alternative form, the control cam includes an air ejection camming stage and a blood drawing camming stage, respectively.

In this form, the air ejection and blood drawing camming stages are arranged successively between the charge drawing and ejection camming stages. In particular, the air ejection camming stage succeeds the detent camming stage adjacent the end of the charge drawing camming stage, and the blood drawing camming stage precedes the charge ejection camming stage.

In this form, each of the air ejection and blood drawing camming stage prevent substantial longitudinal movement of the syringe body relative to the casing, but permit rotation of the body as with the charge control and ejection

control camming stages. During those movements, the plunger is able to eject air from the needle and draw blood from the vein into the needle. Again, those movements can occur and be completed during initial movement of the plunger, in this form.

In order to achieve the relative movement of the body and casing, the camming surfaces of the air ejection and blood drawing camming stages extend at angles to the longitudinal axis of the syringe. In this way, engagement with the cam follower forces the body to rotate about the axis.

In order to limit relative movement of the cam and cam follower, to the respective camming stages until air ejection and blood drawing is respectively completed, the control cam includes additional detent stages adjacent the ends of the air ejection and blood drawing camming stages. In this form, those detent stages are of the same general configuration as the detent stages adjacent the ends of the charge control and ejection control camming stages.

In one preferred form, the control cam follower further includes a disabling camming stage. That section succeeds the ejection control camming stage. In particular, the disabling camming stage extends from the further detent stage adjacent the end of the ejection control camming stage to the exit end of the camming groove or slot. Travel of the cam follower along that disabling camming stage causes the body to move from the disabling position to the disabled position, in this form.

In this form, the disabling camming stage permits longitudinal movement of the body relative to the casing and retraction of the needle into the casing. To that end, the camming surface of disabling camming stage can extend at least generally longitudinally of the syringe, although alternatively can also be angled relative to the longitudinal axis of the syringe. In any event, the cam follower is caused to exit from the camming groove or slot, so as to release the body for movement longitudinally relative to the casing.

In one preferred form, the syringe is initially supplied in the enabled position, i.e. with the body positioned toward the forward end of the casing. In that form, the needle will project from the casing.

However, in an alternative form, it may be desirable to supply the syringe with the body positioned away from the forward end of the casing so that the needle is retracted and housed within the casing. That would protect the needle

from damage or misuse. In that enabling position, the body would need to be moved toward the forward end of the casing so that the syringe is in the enabled position.

In this alternative form, the control cam further includes an enabling camming stage. That camming stage precedes the charge control camming stage, in this form. In particular, the enabling camming stage extends from the entry end of the camming groove or slot toward the charge control camming stage.

In this form, the entry end of the control cam is longitudinally aligned with the cam follower when the body is in the enabling position and before the syringe is enabled. In this way, longitudinal movement of the body toward the forward end of the casing for enablement causes the cam follower to enter and move along the enabling camming stage. Movement of the body relative to the casing is caused by applying a force to the plunger stem in a forward direction. The frictional engagement between the plunger piston and inner face of the syringe body, as well as contact between the plunger piston and forward end of the body, ensures that the body is moved.

In this form, the camming surface of the enabling camming stage of the cam extends at an angle to the longitudinal axis of the syringe. In this way, engagement with the cam follower forces the body to rotate about the axis. As a result of the relative movement between the cam and cam follower, the cam follower is moved out of alignment with the entry end of the camming groove or slot, and toward the charge control camming stage.

In the enabled camming stage the plunger position is adjacent the forward end of the body. In order to limit relative movement between the cam and cam follower in the enabling camming stage, until the piston plunger is in that position, the control cam includes another detent stage adjacent the end of the enabling camming stage. Thus, that other detent stage is positioned between the enabling stage and charge control camming stage. In this form, that other detent stage has the same general configuration and function as the previously described detent stages.

In one preferred embodiment, the camming groove or slot is of a generally zig zag configuration. With this configuration, the multiple stages of

the control cam are arranged with the detent stages at the apical points and the camming stages extending successively there between.

In one preferred form, the rearward longitudinal movement of the body, causing retraction of the needle into the casing, can be achieved by reverse manual movement of the plunger. To that end, the plunger stem may be gripped and pulled rearwardly by a user of the syringe, in this form.

However, in a preferred form, that body movement from the disabling position to the disabled position can occur automatically. That is, the body will automatically move rearward if a user simply removes the forward pushing force from the plunger stem and fails to manually pull the stem rearwardly after use of the syringe.

In this form, that body movement is caused by biasing means acting on the body to slidably move the body rearwardly when in the disabling position. That biasing means extends between the body and casing, in one form.

In one preferred form, the biasing means includes a resilient biasing member. In one form, the biasing member is a resilient strip extending between and connected to the body and casing. That strip is resiliently stretched when the body is in its disabling position and acts to pull the body rearwardly into its disabled position upon release of the plunger following syringe use. In one form, the band is connected to the body and casing at or adjacent the rear ends thereof.

In another form, the biasing member is a compression spring positioned between the body and casing at the forward ends thereof. That spring is compressed when the body is in its enabled position and while the body is rotated into its disabling position. However in that disabling position, the cam and cam follower no longer constrain the body against longitudinal movement and so the compression spring acts to bias the body along the casing into its disabled position. In one preferred form, the compression spring is a helically coiled spring.

It should be appreciated that the biasing member will also act during use of the syringe to bias the body toward the rear end of the casing. That bias will be overcome by a manual force applied periodically to the plunger, such as during liquid charge drawing, tending to bias the body toward the forward end of the casing. The resultant of those axially biasing forces will cause engagement

between the cam follower and camming surfaces with which the follower is successively, axially aligned. Those forces will also cause the relative travel between the interengaging follower and cam in the camming stages, in turn effecting movement of the body relative to the casing. That interengagement will continue until the follower is aligned with the exit end of the camming groove or slot, whereupon the follower is free to disengage from the groove or slot under bias of the biasing member so that the body moves to the disabled position.

In at least one preferred form, the retracted needle is prevented from being re-extended out of the casing. Preventing re-extension of the needle minimises the prospect that the syringe could cause injury such as through careless disposal.

In one preferred form, re-extension of the needle is prevented by axially offsetting the needle and access hole in the casing forward end. The extent of offset is selected so that the needle will extend through the hole during use of the syringe, but once retracted into the casing, will misalign with that hole and so be unable to pass back through the hole upon application of a forward force to the plunger. Indeed, that force will cause a leading free end of the needle to press against and possibly embed into the casing forward end thereby destroying the usefulness of the needle.

In another preferred form, re-extension of the needle is prevented by locking means acting on the body to prevent subsequent forward movement when in the disabled position. That locking means acts between the body and casing, in this form.

In one preferred form, the locking means includes at least one locking element on each of the body and casing, the locking elements interengaging when the body moves into its disabled position. Thereby preventing further movement of the body.

In one preferred form, the locking elements are locking teeth. Those locking teeth are located at or adjacent the rear ends of the body and casing, in this form. In one form, a single tooth may be provided on each of the body and casing, whilst in another form, a plurality of teeth arranged in a ratchet formation, may be provided on at least one of the body and casing.

The syringe of the present invention is confined to a single proper use. Reuse of the syringe is effectively prevented. Moreover, following that use, the syringe can be easily rendered harmless, either by the user or, in one form, automatically. As a consequence, the syringe is less likely to cause transmission of diseases through re-use or misuse, or injury.

For assistance at arriving at an understanding of the present invention, an example syringe incorporating the present invention is illustrated in the attached drawings. The preceding description of the syringe may be read with reference to those drawings. However, as the drawings illustrate one example only, their particularity is not to be understood as superseding the generality of the preceding description.

In the drawings:

Fig 1 is a perspective view, partially in section, of a hypodermic syringe according to one example of the present invention, showing the syringe in an enabling position;

Fig 2 is a perspective view of the body of the syringe of Fig 1;

Fig 3 is a longitudinal cross sectional side view of the syringe of Fig 1, showing the syringe being moved into an enabled position;

Fig 4 is a side view similar to Fig 3 of part of the syringe but showing the syringe in an enabled position and the chamber holding a charge of liquid;

Fig 5 is a side view similar to Fig 4 but showing the syringe in an enabled position and air having been ejected from the needle;

Fig 6 is a side view similar to Fig 5 but showing the syringe in an enabled position and blood having been drawn from a vein into the needle;

Fig 7 is a side view similar to Fig 6 but showing the syringe after ejection of the charge from the chamber and the syringe in a disabling position; and,

Fig 8 is a perspective view, partially in section of the syringe of Fig 1 but showing the syringe in a disabled position.

Finally, it is to be understood that various alterations, modifications and/or additions may be made to the syringe without departing from the ambit of the present invention as disclosed herein.

Dated: 25 March 2003
PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
ROBERT BAIRD WATSON

David B Fitzpatrick

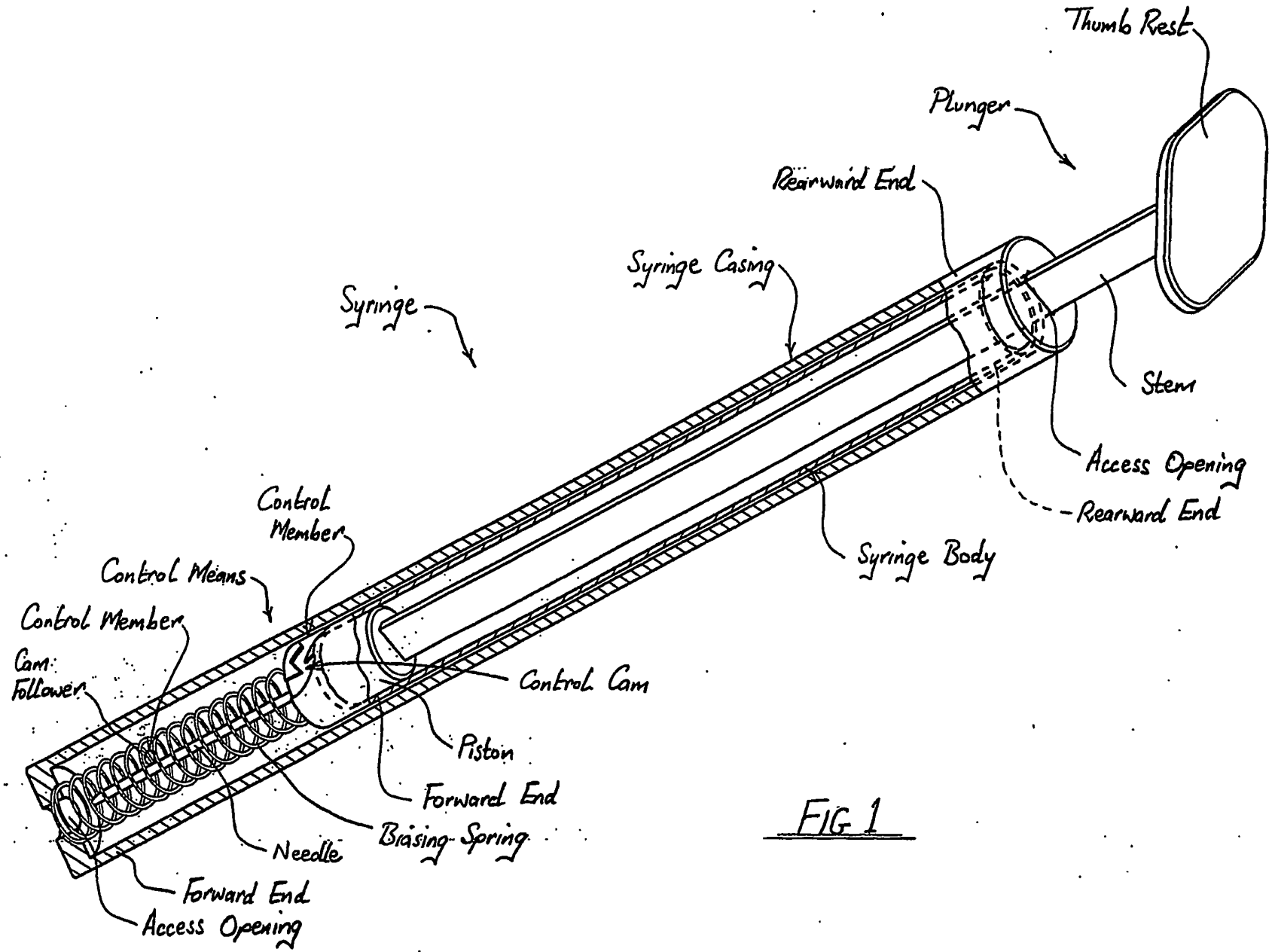
Thumb Rest
Plunger
Rearward End
Syringe Casing
Syringe
Stem
Access Opening
Rearward End
Syringe Body
Control Member
Control Means
Control Member
Cam Follower
Control Cam
Piston
Forward End
Biasing Spring
Needle
Forward End
Access Opening

FIG 1

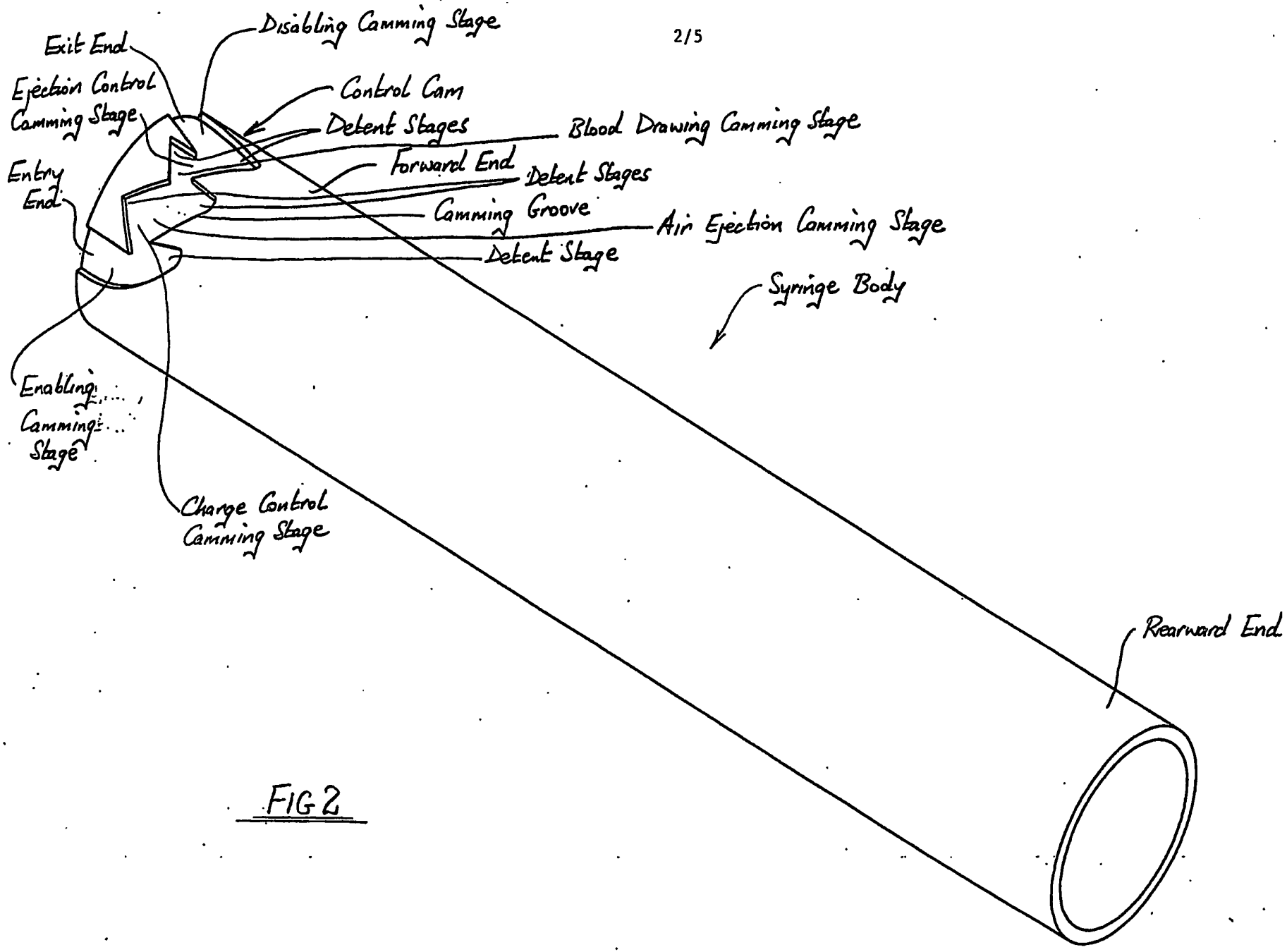
Disabling Camming Stage
Exit End
Ejection Control Camming Stage
Control Cam
Detent Stages
Blood Drawing Camming Stage
Entry End
Forward End
Detent Stages
Camming Groove
Air Ejection Camming Stage
Detent Stage
Syringe Body
Enabling Camming Stage
Charge Control Camming Stage
Rearward End

FIG 2

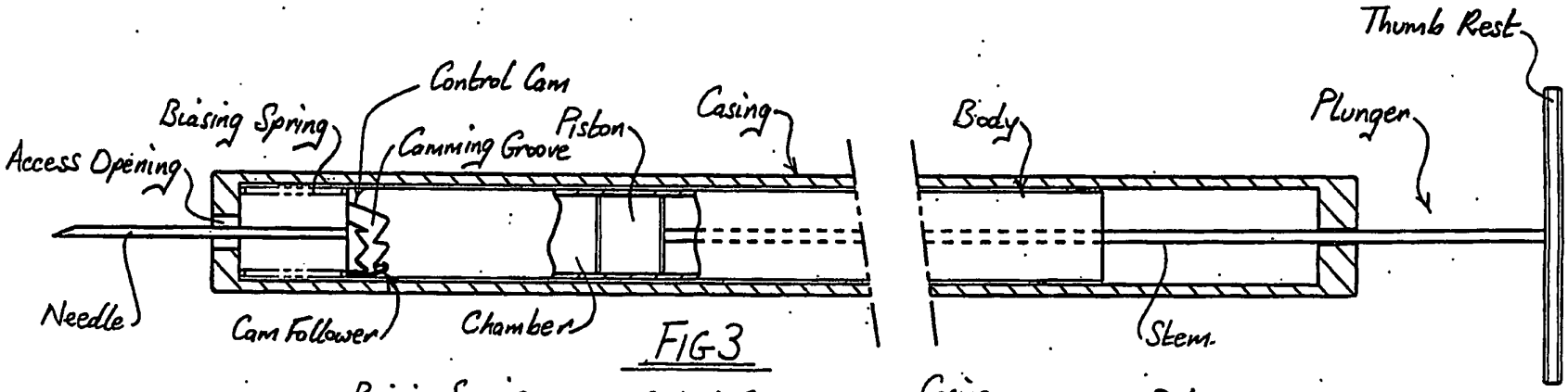

FIG3

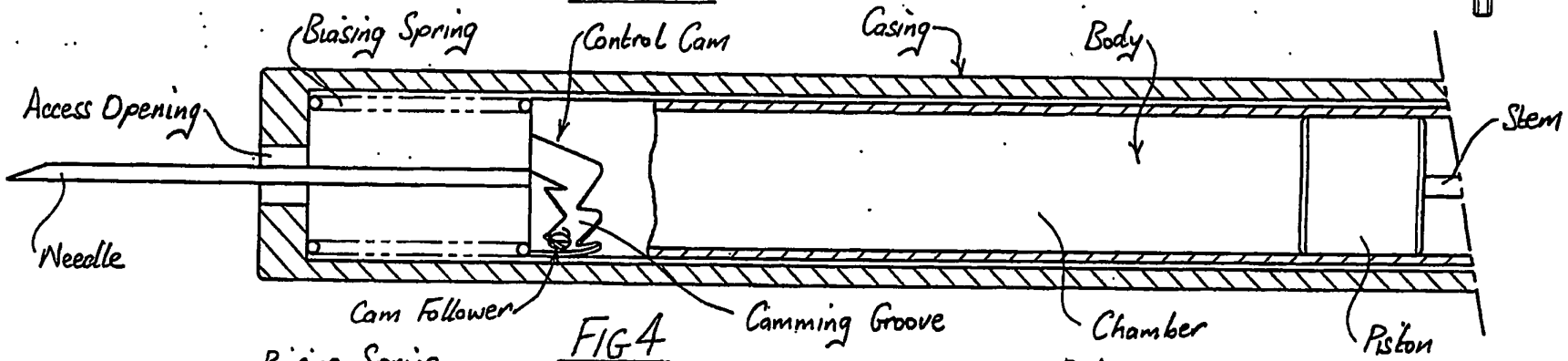

FIG4

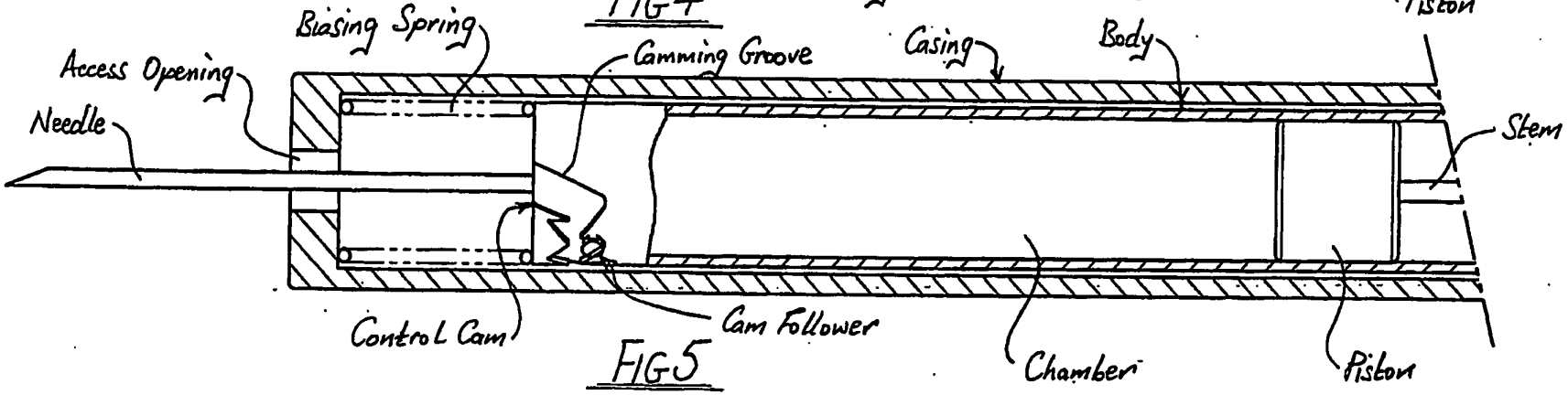

FIG5

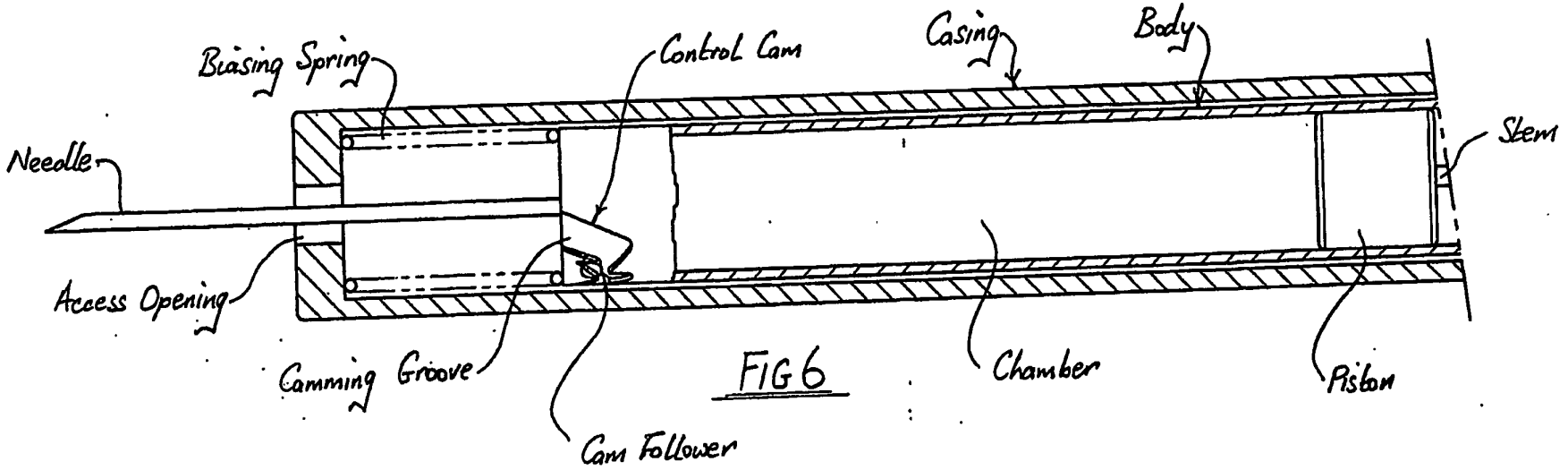
Biasing Spring
Control Cam
Casing
Body
Needle
Stem
Access Opening
Camming Groove
Cam Follower
Chamber
Piston

FIG 6

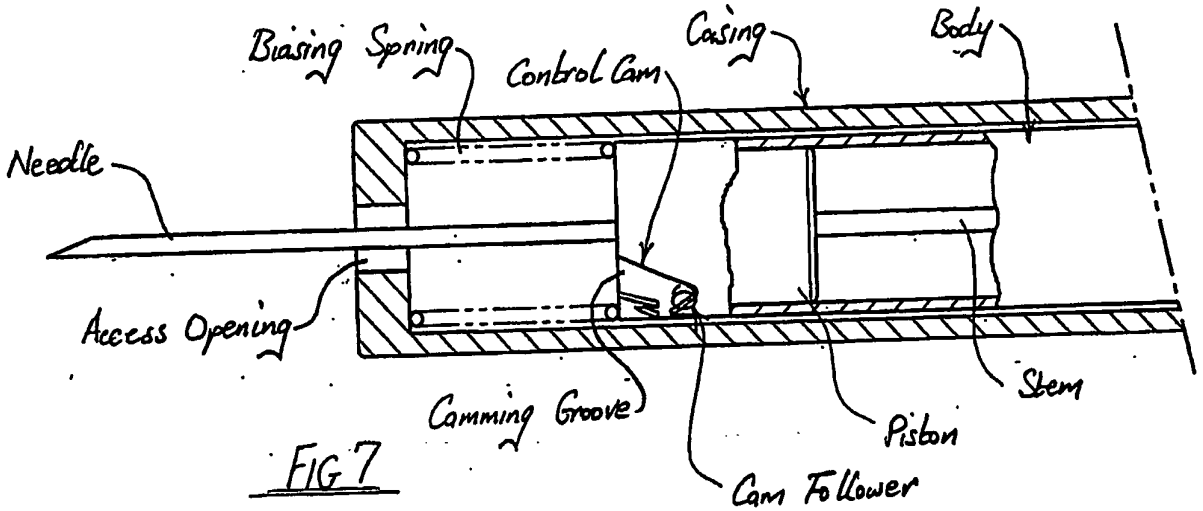
Biasing Spring
Control Cam
Casing
Body
Needle
Access Opening
Camming Groove
Piston
Stem
Cam Follower

FIG 7

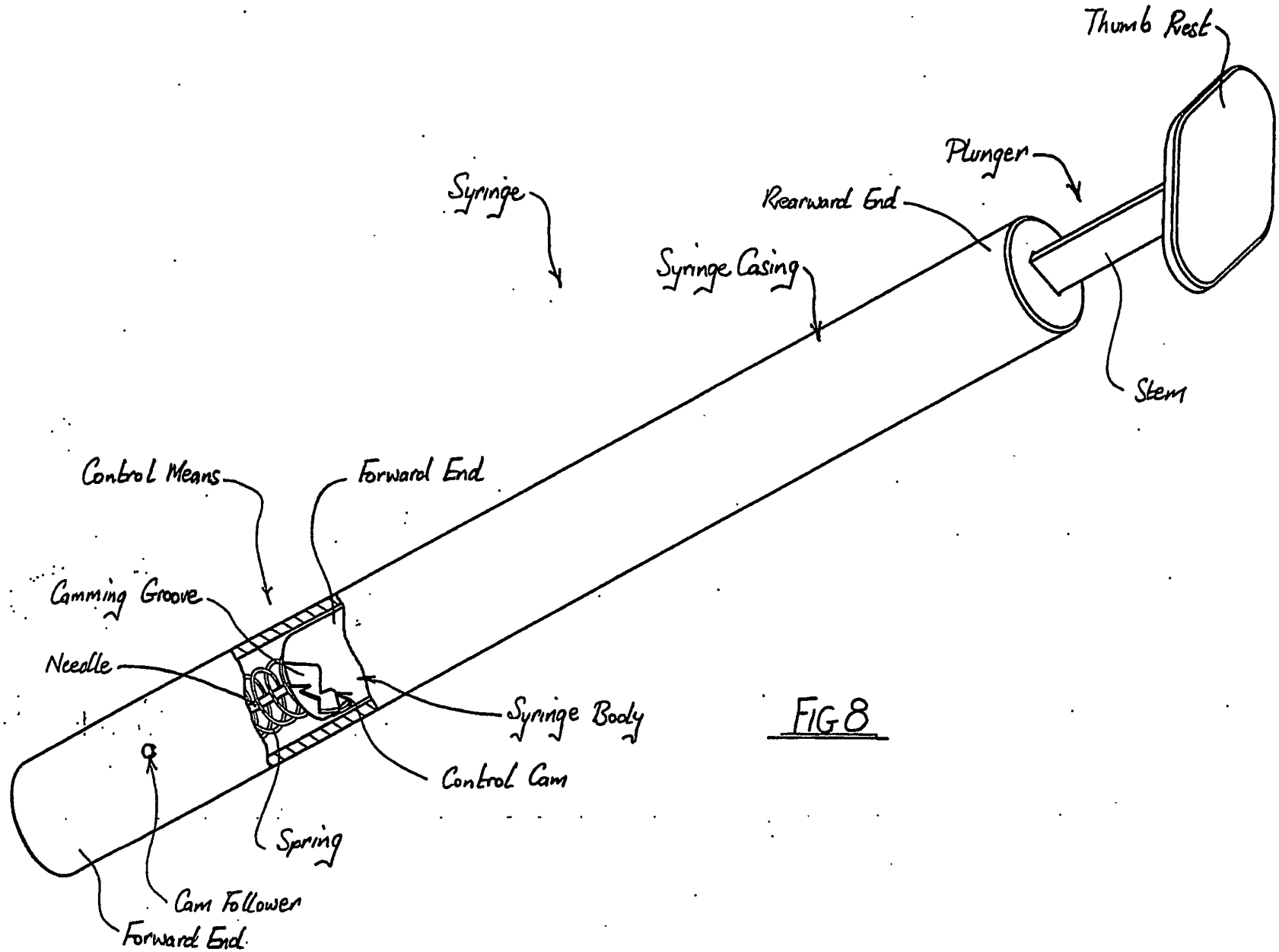
Thumb Rest
Plunger
Syringe
Rearward End
Syringe Casing
Stem
Control Means
Forward End
Camming Groove
Needle
Syringe Body
Control Cam
Spring
Cam Follower
Forward End

FIG 8